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EXAMINER	
HAYES, R	PAPER NUMBER
ART UNIT	6

18M1/0613

FLEHR HOHBACH TEST ALBRITTON & HERBERT
FOUR EMBARCADERO CENTER
SUITE 3400
SAN FRANCISCO CA 94111

1818

DATE MAILED: 06/13/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

for restriction ONLY

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire — month(s), 30 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-17 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☐ Claims _____ are rejected.

5. ☐ Claims _____ are objected to.

6. ☒ Claims 1-17 are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to DNA encoding a DRG11 protein, vectors, host cells, and a method of producing this protein, classified in class 435, subclass 69.1.

II. Claims 8-11, drawn to a recombinant DRG11 protein, classified in class 530, subclass 350.

III. Claim 12, drawn to antibodies of DRG11, classified in Class 530, subclass 387.1.

IV. Claim 13, drawn to methods of detecting DRG11 in a target sample comprising use of antibodies, classified in Class 435, subclass 7.1.

V. Claims 14-17, drawn to methods of detecting DRG11 in different cell types/tissues comprising detecting nucleic acids in different nucleic acid libraries, classified in Class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper, because these products appear to constitute patentably distinct inventions for the following reasons:

Groups I-III are directed to products that are physically and functionally distinct; involving nucleic acids, proteins and antibodies. All of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/purification procedures. For example, the proteins of Group II and antibodies of Group III are fundamentally different molecules than the nucleic acid molecules of Group I, which in turn can be used to clone proteins, make vaccines, or used as therapeutic agents in gene therapy. Although the antibodies of Group III can be used in isolating the proteins of Group II, the antibodies of Group III can be generated by immunizing animals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in affinity chromatography or in immunoassays, or as therapeutic agents themselves. The proteins of Group II can be utilized in making the antibodies of Group III, but not vice versa. In addition, neither the proteins of Group II, nor antibodies of Group III require the vectors and host cells of Group I, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Groups I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids can be used in materially different methods, such as to encode

the full length protein for use in binding assays. In contrast, the method of Group V for detecting differential DRG11 expression using nucleic acid libraries, and determining the differential expression of DRG11 DNA, requires specific tissue or cell preparations and labeled reagents to detect variations in DRG11 expression, which are not required for Group I.

It is noted that the method of Group V does not require the products of Groups II or III, and vice versa.

Groups II-III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown as stated above (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of Group III and the proteins of Group II can be used in other materially different methods, such as in affinity chromatography to isolate other protein molecules, or as therapeutic agents. In contrast, the method of detecting DRG11 protein with antibodies requires different specimens containing DRG11 protein and labeled reagents to detect this protein, which are not required for Group III.

It is noted that the method of Group IV does not require the products of Groups I, and vice versa.

Although there are no provisions under the section for "Relation of Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different methods; restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups IV-V are directed to methods of detecting protein or nucleic acid molecules. Each of these methods require physically and functionally distinct elements. For example, the use of antibodies for the method of Group IV interact with entirely different types of molecules than the nucleic acid molecules used in the method of Group V, and vice versa. Moreover, the method of Group V requires construction of nucleic acid libraries, which are not required in the method of Group IV. These inventions are, therefore, patentably distinct, since one is not required for the other.

3. Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Robin Silva and Richard Trecartin on 5/29 and 5/30/97 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Marian C. Knode

MARIAN C. KNODE
SUPERVISORY PATENT EXAMINER
GROUP 1800

Robert C. Hayes, Ph.D.
June 6, 1997